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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/475,822	06/07/1995	MARC ALIZON	3495.0010-24	4214

22852 7590 06/15/2004

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S-11

<b>Office Action Summary</b>	<b>Application No.</b> 08/475,822	<b>Applicant(s)</b> ALIZON ET AL.	
	<b>Examiner</b> Jeffrey Fredman	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 35-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Objections***

1. The objection to the claims is withdrawn in view of the renumbering.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 35, 37, 39, 41, 43 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

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where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides 4000 and 9000 are presented below.

```
Query: 4010  ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4069
              |||
Sbjct: 4197  ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4256
pol      856  I P Y N P Q S Q G V V E S M N K E L K K
```

```
Query: 4070  ttataggacaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4129
              |||
Sbjct: 4257  ttataggccaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4316
pol      876  I I G Q V R D Q A E H L K T A V Q M A V
```

```
Query: 4130  tcatccacaatttttaaaagaaaaannnnnnnnnnnnnnntacagtgcaggggaaagaatag 4189
              |||
Sbjct: 4317  tcatccacaatttttaaaagaaaaaggggggattggggggtacagtgcaggggaaagaatag 4376
pol      896  F I H N F K R K G G I G G Y S A G E R I
```

```
Query: 4190  tagacataatagcaacagacatacaaactaaagaattacaaaaacaaattacaaaaattc 4249
              |||
Sbjct: 4377  tagacataatagcaacagacatacaaactaaagaattacaaaaacaaattacaaaaattc 4436
pol      916  V D I I A T D I Q T K E L Q K Q I T K I
```

```
Query: 4250  aaaattttcgggtttattacagggacagcagaaatccactttggaaaggaccagcaaagc 4309
              |||
Sbjct: 4437  aaaattttcgggtttattacagggacagcagagatccactttggaaaggaccagcaaagc 4496
pol      936  Q N F R V Y Y R D S R D P L W K G P A K
```

```
Query: 4310  tcctctggaaagggtgaaggggcagtagtaatacaagataatagtgacataaaagtagtgc 4369
```

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|||||  
Sbjct: 4497 tcctctggaaaggtgaagggcagtagtaatacaagataatagtgacataaaagtagtgc 4556  
pol 956 L L W K G E G A V V I Q D N S D I K V V

Query: 4370 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4429  
|||||  
Sbjct: 4557 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4616  
pol 976 P R R K A K I I R D Y G K Q M A G D D C

Query: 4430 tggcaagtagacaggatgaggattagaacatggaaaagttagtaaaacaccatattgtat 4489  
|||||  
Sbjct: 4617 tggcaagtagacaggatgaggattagaacatggaaaagttagtaaaacaccatattgtat 4676  
pol 996 V A S R Q D E D ^^^

Query: 4490 gtttcagggaaagctaggggatgggttttatagacatcactatgaaagccctcatccaaga 4549  
|||||  
Sbjct: 4677 gtttcagggaaagctaggggatgggttttatagacatcactatgaaagccctcatccaaga 4736

Query: 4550 ataagttcagaagtagacacatcccactaggggatgctagattggtaataacaacatattgg 4609  
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Sbjct: 4737 ataagttcagaagtagacacatcccactaggggatgctagattggtaataacaacatattgg 4796

Query: 4610 ggtctgcatacaggagaaagagactggcatttgggtcagggagtctccatagaatggagg 4669  
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Sbjct: 4797 ggtctgcatacaggagaaagagactggcatctgggtcagggagtctccatagaatggagg 4856

Query: 4670 aaaaagagatatagcacacaagtagaccctgaactagcagaccaactaattcatctgtat 4729  
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Sbjct: 4857 aaaaagagatatagcacacaagtagaccctgaactagcagaccaactaattcatctgtat 4916

Query: 4730 tactttgactggtttttcagactctgctataagaaaggccttattaggacacatagtttagc 4789  
|||||  
Sbjct: 4917 tactttgactggtttttcagactctgctataagaaaggccttattaggacacatagtttagc 4976

Query: 4790 cctaggtgtgaatatcaagcaggacataacaaggtaggatctctacaatacttggcacta 4849  
|||||  
Sbjct: 4977 cctaggtgtgaatatcaagcaggacataacaaggtaggatctctacaatacttggcacta 5036

Query: 4850 gcagcattaataacacccaaaaaagataaaagccacctttgcctagtgttacgaaactgaca 4909  
|||||  
Sbjct: 5037 gcagcattaataacacccaaaaaagataaaagccacctttgcctagtgttacgaaactgaca 5096

Query: 4910 gaggatagatggaacaagccccagaagaccaagggccacagaggagccacacaatgaat 4969  
|||||

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Sbjct: 5097 gaggatagatggaacaagccccagaagaccaagggccacagagggagccacacaatgaat 5156

Query: 4970 ggacactagagccttttagaggagccttaagaatgaagctggttagacattttcctaggattt 5029  
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Sbjct: 5157 ggacactagagccttttagaggagccttaagaatgaanctggttagacattttcctaggattt 5216

Query: 5030 ggctccatggccttagggcaacatatctatgaaacttatggggatacttgggcaggagtgg 5089  
|||||

Sbjct: 5217 ggctccatggccttagggcaacatatctatgaaacttatggggatacttgggcaggagtgg 5276

Query: 5090 aagccataataagaattctgcaacaactgctgtttatccattttcagaattgggtgtcga 5149  
|||||

Sbjct: 5277 aagccataataagaattctgcaacaactgntgtttatcca-tttcagaattgggtgtcga 5335

Query: 5150 catagcagaataggcggttactcgacagaggagagcaagaaatggagccagtagatcctag 5209  
|||||

Sbjct: 5336 catagcagaataggcggttactcaacagaggagagcaagaaatggagccagtagatcctag 5395

Query: 5210 actagagccctggaagcatccaggaagtcagcctaaaactgcttgtaccaattgctattg 5269  
|||||

Sbjct: 5396 actaganccctggaagcatccaggaagtcagcctaaaactgcttgtaccacttnntattg 5455

Query: 5270 taaaaagtgttgcttttcattgccaaagtttgtttcataacaaaagccttaggcattctccta 5329  
|||||

Sbjct: 5456 taaaaagtgttgcttttcattgccaaagtttgtttcacacaaaagccttaggcattctccta 5515  
orfQ 1 C Q V C F T T K A L G I S Y

Query: 5330 tggcaggaagaagcggagacagcgacgaagacctcctcaaggcagtcagactcatcaagt 5389  
|||||

Sbjct: 5516 tggcannaagaagcggagacagcgacgaagacctcctcaaggcagtcagactcatcaagt 5575  
orfQ 15 G X K K R R Q R R R P P Q G S Q T H Q V

Query: 5390 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaataagcaatagtagc 5449  
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Sbjct: 5576 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaataagcaatagcagc 5635  
orfQ 35 S L S K Q ^^^

Query: 5450 attagtagtagcaataataatagcaatagttgtgtgggtccatagtaatcatagaatatag 5509  
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Sbjct: 5636 attagtagtagcaataataatagcaatagttgtgtgggtccatagtaatcatagaatatag 5695

Query: 5510 gaaaatattaagacaaagaaaaatagacagggttaattgatagactaatagaaagagcaga 5569  
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Sbjct: 5696 gaaaatattaagacaaagaaaaatagacagggttaattgatagactaatagaaagagcaga 5755

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env 1 K E Q

Query: 5570 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggagat 5629  
|||||  
Sbjct: 5756 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggaaat 5815  
env 4 K T V A M R V K E K Y Q H L W R W G W K

Query: 5630 ggggcaccatgctccttgggatgttgatgatctgtagtgctacagaaaaattgtgggtca 5689  
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Sbjct: 5816 ggggcaccatgctccttgggatattgatgatctgtagtgctacagaaaaattgtgggtca 5875  
env 24 W G T M L L G I L M I C S A T E K L W V

Query: 5690 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5749  
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Sbjct: 5876 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5935  
env 44 T V Y Y G V P V W K E A T T T L F C A S

Query: 5750 atgctaaagcatatgatacagaggtacataatgtttgggccacacatgcctgtgtaccca 5809  
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Sbjct: 5936 atgctaaagcatatgatacagaggtacataatgtttgggccacacatgcctgtgtaccca 5995  
env 64 D A K A Y D T E V H N V W A T H A C V P

Query: 5810 cagaccccaacccacaagaagtagtattggtaaagtgtgacagaaaattttaacatgtgga 5869  
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Sbjct: 5996 cagaccccaacccacaagaagtagtattggtaaagtgtgacagaaaattttaacatgtgga 6055  
env 84 T D P N P Q E V V L V N V T E N F N M W

Query: 5870 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 5929  
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Sbjct: 6056 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 6115  
env 104 K N D M V E Q M H E D I I S L W D Q S L

Query: 5930 agccatgtgtataaaattaacccccactctgtgttagtttaaagtgcactgatttgaagaatg 5989  
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Sbjct: 6116 agccatgtgtataaaattaacccccactctgtgttagtttaaagtgcactgatttggggaatg 6175  
env 124 K P C V K L T P L C V S L K C T D L G N

Query: 5994 taataccaatagtagtagcggggagaatgataatggagaaaggagagataaaaaactgctc 6053  
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Sbjct: 6195 taataccaatagtagtagcggggaaatgatgatggagaaaggagagataaaaaactgctc 6254  
env 151 N T N S S S G E M M M E K G E I K N C S

Query: 6054 tttcaatatcagcacaaagcataagaggtaagggtgcagaaagaatatgcannnnnnnataa 6113  
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Sbjct: 6255 tttcaatatcagcacaaagcataagaggttaaggtgcagaaagaatatgcatttttttataa 6314  
env 171 F N I S T S I R G K V Q K E Y A F F Y K

Query: 6114 acttgatataataaccaatagataatgatactaccagctatacgttgacaagttgtaacac 6173  
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Sbjct: 6315 acttgatataataaccaatagataatgatactaccagctatacgttgacaagttgtaacac 6374  
env 191 L D I I P I D N D T T S Y T L T S C N T

Query: 6174 ctcagtcattacacaggcctgtccaaagggtatcctttgagccaattcccatacattattg 6233  
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Sbjct: 6375 ctcagtcattacacaggcctgtccaaagggtatcctttgagccaattcccatacattattg 6434  
env 211 S V I T Q A C P K V S F E P I P I H Y C

Query: 6234 tgccccggctggtttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6293  
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Sbjct: 6435 tgccccggctggtttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6494  
env 231 A P A G F A I L K C N N K T F N G T G P

Query: 6294 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6353  
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Sbjct: 6495 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6554  
env 251 C T N V S T V Q C T H G I R P V V S T Q

Query: 6354 actgctgttaaatggcagctctggcagaagaagaggtagtaattagatctgccaatttcac 6413  
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Sbjct: 6555 actgctgttgaatggcagctctagcagaagaagaggtagtaattagatctgccaatttcac 6614  
env 271 L L L N G S L A E E E V V I R S A N F T

Query: 6414 agacaatgctaaaaccataatagtacagctgaaccaatctgtagaaattaattgtacaag 6473  
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Sbjct: 6615 agacaatgctaaaaccataatagtacagctgaaccaatctgtagaaattaattgtacaag 6674  
env 291 D N A K T I I V Q L N Q S V E I N C T R

Query: 6474 acccaacaacaataacaagaaaaagtatccgtatccagagaggaccagggagagcatttgt 6533  
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Sbjct: 6675 acccaacaacaataacaagaaaaagtatccgtatccagaggggaccagggagagcatttgt 6734  
env 311 P N N N T R K S I R I Q R G P G R A F V

Query: 6534 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6593  
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Sbjct: 6735 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6794  
env 331 T I G K I G N M R Q A H C N I S R A K W

Query: 6594 gaataacacttttaaacagatagatagcaaattaagagaacaatttggaaataataaaac 6653  
|||||

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Sbjct: 6795 gaatgccacttttaaacagatagctagcaaattaagagaacaatttggaataataaaac 6854  
env 351 N A T L K Q I A S K L R E Q F G N N K T

Query: 6654 aataatctttaagcagtcctcaggaggggacccagaaattgtaacgcacagttttaattg 6713  
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Sbjct: 6855 aataatctttaagcaatcctcaggaggggacccagaaattgtaacgcacagttttaattg 6914  
env 371 I I F K Q S S G G D P E I V T H S F N C

Query: 6714 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6773  
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Sbjct: 6915 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6974  
env 391 G G E F F Y C N S T Q L F N S T W F N S

Query: 6774 tacttgggagtactaaaggggtcaaataacactgaaggaagtgaacacaatcacctcccatg 6833  
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Sbjct: 6975 tacttgggagtactgaaggggtcaaataacactgaaggaagtgaacacaatcacactcccatg 7034  
env 411 T W S T E G S N N T E G S D T I T L P C

Query: 6834 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 6893  
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Sbjct: 7035 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 7094  
env 431 R I K Q F I N M W Q E V G K A M Y A P P

Query: 6894 catcagtggaacaaattagatgttcatcaaataattacagggctgctattaacaagagatgg 6953  
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Sbjct: 7095 catcagcggacaaattagatgttcatcaaataattacagggctgctattaacaagagatgg 7154  
env 451 I S G Q I R C S S N I T G L L L T R D G

Query: 6954 tggtaatagcaacaatgagtcagagatcttcagacctggaggaggagatatgagggacaa 7013  
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Sbjct: 7155 tggtaatatacaacaatgggtccgagatcttcagacctggaggaggagatatgagggacaa 7214  
env 471 G N N N N G S E I F R P G G G D M R D N

Query: 7014 ttggagaagtgaattatataaatataaagtagtaaaaattgaaccattaggagtagcacc 7073  
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Sbjct: 7215 ttggagaagtgaattatataaatataaagtagtaaaaattgaaccattaggagtagcacc 7274  
env 491 W R S E L Y K Y K V V K I E P L G V A P

Query: 7074 caccaaggcaaagagaagagtggtgcagagagaaaaaagagcagtggggaataggagcttt 7133  
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Sbjct: 7275 caccaaggcaaagagaagagtggtgcagagagaaaaaagagcagtggggaataggagcttt 7334  
env 511 T K A K R R V V Q R E K R A V G I G A L

Query: 7134 gttccttgggttcttgggagcagcaggaagcactatgggcgcagcgtcaatgacgctgac 7193  
|||||

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Sbjct: 7335 gttccttgggttcttgggagcagcaggaagcactatgggcgcacggtcaatgacgctgac 7394  
env 531 F L G F L G A A G S T M G A R S M T L T

Query: 7194 ggtacaggccagacaattattgtctggtatagtgcagcagcagaacaatttgctgagggc 7253  
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Sbjct: 7395 ggtacaggccagacaattattgtctggtatagtgcagcagcagaacaatttgctgagggc 7454  
env 551 V Q A R Q L L S G I V Q Q Q N N L L R A

Query: 7254 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7313  
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Sbjct: 7455 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7514  
env 571 I E A Q Q H L L Q L T V W G I K Q L Q A

Query: 7314 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctggggatttgggggttg 7373  
|||||  
Sbjct: 7515 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctgggnatttgggggttg 7574  
env 591 R I L A V E R Y L K D Q Q L L G I W G C

Query: 7374 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7433  
|||||  
Sbjct: 7575 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7634  
env 611 S G K L I C T T A V P W N A S W S N K S

Query: 7434 tctggaacagatttgggaataacatgacctggatggagtgggacagagaaattaacaatta 7493  
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Sbjct: 7635 tctggaacagatttgggaataacatgacctggatggagtgggacagagaaattaacaatta 7694  
env 631 L E Q I W N N M T W M E W D R E I N N Y

Query: 7494 cacaagcttaatacactccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7553  
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Sbjct: 7695 cacaagcttaatacattccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7754  
env 651 T S L I H S L I E E S Q N Q Q E K N E Q

Query: 7554 agaattattggaattagataaatgggcaagtttgtggaattggtttaacataacaaattg 7613  
|||||  
Sbjct: 7755 agaattattggaattagataaatgggcaagtttgtggaattggtttaacataacaaattg 7814  
env 671 E L L E L D K W A S L W N W F N I T N W

Query: 7614 gctgtggtatataaaaattattcataatgatagtaggaggcttggttaggtttaagaatagt 7673  
|||||  
Sbjct: 7815 gctgtggtatataaaaattattcataatgatagtaggaggcttggttaggtttaagaatagt 7874  
env 691 L W Y I K I F I M I V G G L V G L R I V

Query: 7674 ttttgctgtactttctgtagtgaatagagttaggcagggatattcaccattatcgtttca 7733  
|||||

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Sbjct: 7875 ttttgctgtacttttctatagtgaaatagagtttaggcagggatattcaccattatcgttttca 7934  
env 711 F A V L S I V N R V R Q G Y S P L S F Q

Query: 7734 gacccacctcccaatccccgaggggacccgacagggcccgaaggaatagaagaagaaggtgg 7793  
|||||  
Sbjct: 7935 gacccacctcccaacccccgaggggacccgacagggcccgaaggaatagaagaagaaggtgg 7994  
env 731 T H L P T P R G P D R P E G I E E E G G

Query: 7794 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 7853  
|||||  
Sbjct: 7995 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 8054  
env 751 E R D R D R S I R L V N G S L A L I W D

Query: 7854 cgatctgcggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 7913  
|||||  
Sbjct: 8055 cgatctgcggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 8114  
env 771 D L R S L C L F S Y H R L R D L L L I V

Query: 7914 aacgaggattgtggaacttctgggacgcaggggggtgggaagccctcaaattattggtggaa 7973  
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Sbjct: 8115 aacgaggattgtggaacttctgggacgcaggggggtgggaagccctcaaattattggtggaa 8174  
env 791 T R I V E L L G R R G W E A L K Y W W N

Query: 7974 tctcctacagtattggagtcaggagctaaagaatagtgtgttagcttgcataatgccac 8033  
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Sbjct: 8175 tctcctacagtattggagtcagggaactaaagaatagtgtgttagcttgcataatgccac 8234  
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Query: 8034 agctatagcagtagctgaggggacagatagggttatagaagtagtacaaggagcttatag 8093  
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Query: 8094 agctattcgccacatacctagaagaataagacagggccttggaaggattttgctataaga 8153  
|||||  
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orfF 1 D R A W K G F C Y K  
env 851 A I R H I P R R I R Q G L E R I L L ^^^

Query: 8154 tgggtggcaagtgggtcaaaaagtagtgtgggttgatggcctgctgtaagggaaagaatga 8213  
|||||  
Sbjct: 8355 tgggtggcaagtgggtcaaaaagtagtgtgggttgatggcctactgtaagggaaagaatga 8414  
orfF 11 M G G K W S K S S V V G W P T V R E R M

Query: 8214 gacgagctgagccagcagcagatgggggtgggagcagcatctcgagacctagaaaaacatg 8273

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|||||  
Sbjct: 8415 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctggaaaaacatg 8474  
orfF 31 R R A E P A A D G V G A A S R D L E K H

Query: 8274 gagcaatcacaagtagcaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333  
|||||  
Sbjct: 8475 gagcaatcacaagtagcaatacagcagctaccaatgctgcttgtgcctggctagaagcac 8534  
orfF 51 G A I T S S N T A A T N A A C A W L E A

Query: 8334 aagaggaggaggaggtgggttttccagtcacacctcaggtacctttaagaccaatgactt 8393  
|||||  
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orfF 71 Q E E E E V G F P L T P Q V P L R P M T

Query: 8394 acaaggcagctgtagatcttagccactttttaaaagaaaaggggggactggaagggctaa 8453  
|||||  
Sbjct: 8595 acaaggcagctgtagatcttagccactttttaaaagaaaaggggggactggaagggctaa 8654  
orfF 91 Y K A A V D L S H F L K E K G G L E G L

Query: 8454 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8513  
|||||  
Sbjct: 8655 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714  
orfF 111 I H S Q R R Q D I L D L W I Y H T Q G Y

Query: 8514 tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573  
|||||  
Sbjct: 8715 tccctgattggcagaactacacaccagggccaggggtcagatatccactgacctttggat 8774  
orfF 131 F P D W Q N Y T P G P G V R Y P L T F G

Query: 8574 ggtgctacaagctagtagcaggttagccagagaaggttagaagaagccaacaaaggagaga 8633  
|||||  
Sbjct: 8775 ggtgctacaagctagtagcaggttagccagataaggttagaagaggccaataaaggagaga 8834  
orfF 151 W C Y K L V P V E P D K V E E A N K G E

Query: 8634 acaccagcttggttacaccctgtgagcctgcatggaatggatgacccggagagagaagtgt 8693  
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Sbjct: 8835 acaccagcttggttacaccctgtgagcctgcatggaatggatgacccggagagagaagtgt 8894  
orfF 171 N T S L L H P V S L H G M D D P E R E V

Query: 8694 tagagtggaggtttgacagccgcctagcatttcacatgagcccgagagctgcatccgg 8753  
|||||  
Sbjct: 8895 tagagtggaggtttgacagccgcctagcatttcacatgagcccgagagctgcatccgg 8954  
orfF 191 L E W R F D S R L A F H H V A R E L H P

Query: 8754 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 8813

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          |||||||
Sbjct: 8955 agtactttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 9014
orfF  211  E  Y  F  K  N  C  ^^^

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Query: 8814 cagggagggcgtggcctgggcgggactggggagtggcgagccctcagatcctgcatataag 8873
          |||||||
Sbjct: 9015 cagggagggcgtggcctggccgggactggggagtggcgagccctcagatgctgcatataa 9074

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Query: 8874 cagctgctttttgcctgtactgggtctctctggtttagaccagatctgagcctgggagctc 8933
          |||||||
Sbjct: 9075 cagctgctttttgcctgtactgggtctctctggtttagaccagatttgagcctgggagctc 9134

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Score = 2796 bits (1454), Expect = 0.0  
 Identities = 1477/1489 (99%)  
 Strand = Plus / Plus

It is noted that with regard to, for example, the sequence region between nucleotides 4487 and 5086 claimed in claim 11, there are two nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 599 nucleotide sequence which is the first sequence of claim 1, two errors would represent approximately a 0.3% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

With regard to the kit claims, it is noted that the preamble phrase "a kit" imposes no structural requirements upon the product claims.

With regard to the issue of the new limitation, a cell free supernatant comprising cells infected with HIV-1, it is noted that the website at the following address

<http://www.nyscience.org/whataboutaids/protect/anyone/content.html> states "Extremely

small numbers of infected white blood cells can also be found in saliva.” Therefore, when Chang teaches analysis of saliva, Chang is inherently teaching a method in which a substantially cell free biological fluid is detected which fluid comprises cells infected with HIV-1.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 35-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977) as applied to claims 35, 37, 39, 41, 43 and 45 as discussed above and further in view of White et al (U.S. Patent 4,677,054).

Chang teaches the limitations of claims 35, 37, 39, 41, 43 and 45 as discussed above, including detection of HIV-1 using nucleic acid probes by dot blotting.

With regard to the issue of the new limitation, a cell free supernatant comprising cells infected with HIV-1, it is noted that the website at the following address

<http://www.nyscience.org/whataboutaids/protect/anyone/content.html> states "Extremely small numbers of infected white blood cells can also be found in saliva." Therefore, when Chang teaches analysis of saliva, Chang is inherently teaching a method in which a substantially cell free biological fluid is detected which fluid comprises cells infected with HIV-1.

Chang does not teach the use of labels on the probes.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

Further with regard to the new limitation, White expressly teaches analysis of supernatants of cells by lysing the cells (see column 3, line 18) followed by centrifugation and analysis of the supernatant (see column 3, lines 25-50). Finally,

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White clearly recognizes that the method may be applied to virally infected cells (see column 1, lines 59-61 where White discussed EBV infected cells).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Chang because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the labels of White to detect HIV as taught by Chang since White says that the method is broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

***Claim Rejections - 35 USC § 112 – Written Description***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Claim 47 is a generic claim which is based upon a single species. That is, Applicant identified a single HIV-1 sequence. However, claim 47 encompasses a genus of any HIV-1 nucleic acid anywhere, which genus comprises each of the hundreds of millions of different variants which exist around the world. These HIV-1 variants are not disclosed in the specification resulting in a genus which includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only a single HIV-1 sequence. Thus, applicant has express possession of only a single HIV-1 sequence in a genus which comprises hundreds of millions of different possibilities.

The claim indicates no common element or attributes of the sequences that is required. No structural domains such as specific amino acid sequences (found in claim 48), or functional domains or any common attribute whatsoever is required. Simply a virus which shares the same name as that identified by Applicant (and regarding which Applicant lost an interference to Chang et al regarding priority). Claim 47 has no

structural limitations or requirements which provide guidance on the identification of sequences which even distinguish, in a structural way, HIV-1 from any other similar lentivirus such as SIV. Claim 47 provides no written description of alleles, of insertions, of deletions or of any other variation in the HIV-1 sequence.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

“A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. “

In the current situation, the definition of the sequence as an HIV-1 sequence, without any specific structure given in claim 47, is precisely the situation of naming a type of material which is generally known to likely exist, but except for the single specific example of a particular HIV-1 sequence provided in the specification, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim.

It is noted that in *Fiers v. Sugano* (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely by its functional utility, as an HIV-1 sequence, without any definition of the particular sequences claimed. Claim 47 envisions a scope which encompasses any HIV-1 sequence but the specification does not provide the detailed chemical structure of any DNA other than the single HIV-1 sequence described.

In the instant application, a single specific sequence is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than the single sequence expressly disclosed. Therefore, claim 47 fails to meet the written description requirement by encompassing sequences which are not described in the specification.

***Claim Rejections - 35 USC § 112 – Enablement***

10. Claim 47 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of the specific HIV-1 sequence disclosed in the specification, does not reasonably provide enablement for detection of

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HIV-1 variants which are not disclosed in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

#### The nature of the invention

The claims are drawn to a methods of detecting the presence of HIV-1 in a subject comprising the steps of detecting HIV-1 nucleic acids present in the supernatant of a biological sample. The invention is in a class of invention which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

#### The breadth of the claims

The claims encompass diagnosis of any HIV-1 virus, whether there is significant shared sequence or not. The claim includes no structural elements whatsoever regarding the Human Immunodeficiency virus. No specific polymorphisms in HIV-1 or sequence alterations are identified. The claims encompass any insertion, any deletion, any substitution or any alteration whatsoever relative to the HIV-1 sequence disclosed

in the specification. No specific sequences are recited for the HIV-1 sequences are provided so these claim terms broadly encompass any sequence which can be so named.

#### Quantity of Experimentation

The quantity of experimentation in this area is extremely large since determination of the diagnostic efficacy of any particular HIV-1 sequence with relation to the presence of the virus would require identification of a disease cohort, since different individuals are infected with different subtypes of the HIV-1 virus and different probes would function to detect different subtypes or other variants. In the case of HIV-1 polymorphisms, deletions, insertions and other sequence alterations, analysis of the entire cohort for the alteration would be required and performance of this method on a large enough sample to be statistically significant. This would require significant inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

#### The unpredictability of the art and the state of the prior art

The prior art shows that a probe which detects one strain of HIV-1 may fail to detect other HIV-1 strains. Candotti et al (AIDS (1991) 5(8):1003-7) notes "Moreover, the DNA amplified from two other isolates did not hybridize with the corresponding probe despite efficient PCR. Base substitutions were detected in the regions of proviral genomes involved in oligonucleotide annealing and were assumed to be responsible for the **failure** of both amplification and probing. Our data confirm that the genetic variability of HIV-1 may reduce the efficiency of PCR as a diagnostic procedure,

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especially in the case of African isolates (emphasis added).” So even 8 years after the filing date of the specification from which priority is claimed, there was significant variability in the detection of HIV-1 using HIV-1 nucleic acids. This unpredictability is heightened with regard to the current application which was written in a time when oligonucleotide synthesis was uncertain and difficult, the PCR method used by Candotti had not yet been invented, and probe synthesis, selection and detection methods were significantly more primitive than they were in 1991, much less now in 2004.

#### Working Examples

The specification has one working example of an HIV-1 sequence. There are no other working examples.

#### Guidance in the Specification.

The specification, while providing a general review of methods to diagnose HIV-1 does not provide teachings sufficient to overcome doubts raised in the art with regards to the unpredictability of probes to function and with regard to the absence of any sequence for any HIV-1 other than the single sequence disclosed. It would essentially be a trial and error process to make and use the many possible diverse species of HIV-1 encompassed by the claims in order to diagnose disease.

#### Level of Skill in the Art

The level of skill in the art is deemed to be high.

#### Conclusion

In the instant case, as discussed above, the level of unpredictability in the art is high as shown by the cited prior art, the specification provides one with little description

or guidance that leads one to a reliable method of diagnosis of HIV-1. One of skill in the art cannot readily anticipate the effect of a change within the subject matter to which the claimed invention pertains. Further the specification does not provide guidance to overcome art recognized problems in diagnosis required to actually use the diagnostic methods as broadly claimed for all HIV-1 nucleic acids whatever their sequence. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the small number of working examples and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

### ***Response to Arguments***

11. Applicant's arguments filed April 23, 2004 have been fully considered but they are not persuasive.

Applicant reiterates the argument that the sequences of Chang and the instant application are different. This argument has been addressed previously. In short, the issue in the current case is simply one of fact. Are the sequences the same or not? The examiner has read portions of John Crewdson's book "Science Fictions", which discusses the original studies on HIV in 1984. Crewdson quotes Wong-Staal, a coinventor on the Chang patent, as saying "that LAV and HTLV-3 are independent isolations of the same virus (see page 165)." Crewdson further notes "They had come from the same patient (see page 165)."

Richterich provides evidence that the differences between the sequences fall within the range of sequencing error. The evidence of differences is not commensurate in scope with the necessary showing because the references cited by Applicant did not perform a side by side comparison of the two viruses from the two laboratories. So since the evidence shows the viruses were identical, the prior art rejections are maintained.

With regard to Applicant's attempt to claim priority to a prior application, Applicant is reminded that they lost the interference. Thus, under the principle of res judicata, priority of invention to Chang has already been awarded and Applicant can no longer contest this point. Chang is, per se, prior art and remains applicable to these claims.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1637  
*6/16/09*